

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Remkes et al.
SERIAL NO. : 10/543,174
FILED : July 22, 2005
FOR : METHOD AND DEVICE FOR SUPPLY OF A DIALYSIS UNIT
WITH DIALYSIS FLUID
GROUP ART UNIT : 1777
EXAMINER : Bass, Dirk
CONFIRMATION NO: 7919

Mail Stop Appeal Brief- Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLACEMENT APPEAL BRIEF UNDER 37 CFR 41.37

Sir:

In response to the Notification of Non-Compliant Appeal Brief of January 31, 2011, for which a response is due February 28, 2011, and in response to the Final Office Action of July 13, 2010 and the Advisory Action of September 3, 2010, Applicant submits this corrected appeal brief in the above-referenced application. A Notice of Appeal with the appropriate fee was previously filed on November 11, 2010. The Office is hereby authorized to charge any fees necessary for consideration of this paper to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

REAL PARTY IN INTEREST

Fresenius Medical Care Deutschland GMBH, the assignee of record, is the real party in interest for all issues related to this application. The assignment is recorded at reel 017620, frame 0697.

RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings known to Appellants, Appellants' legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 16-40 are currently pending. Claims 1-15 were previously cancelled. Claims 16-22, 31-34 and 36-38 are currently withdrawn as directed to a non-elected invention.

Claims 23-30, 35, 39 and 40 stand finally rejected and are subject to appeal.

STATUS OF AMENDMENTS

An amendment was filed on August 5, 2010 subsequent to the final rejection. It is believed that this amendment was entered as the Examiner initialed this amendment "OK to Enter" on August 31, 2010 as shown in PAIR and confirmed in a telephone call with the Examiner on December 22, 2010.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 23 is directed to an apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid. Specifically, with reference to example embodiments within the scope of claim 23 described in the specification and illustrated in the figures, claim 23 is directed to an apparatus for supplying a dialyser (1) of a dialysis unit with a dialysing fluid comprising:

- at least one receiving unit (canister 12, bag 13) for receiving only at least one dialysing fluid concentrate (K1, K2) (page 6, lines 10-12¹; Fig. 1);
- means (38) for providing water (W) for a dilution of the at least one dialysing fluid concentrate (page 6, lines 17-18; Fig. 1);
- means (mixing chamber 15 and proportioning pumps 17, 18, 20) for mixing the at least one dialysing fluid concentrate (K1, K2) and the water (W) in a first pre-set volumetric ratio to prepare the dialysing fluid (page 7, lines 29-32), said means for mixing (15, 17, 18, 20) connected to the at least one receiving unit (12, 13) and configured to receive the at least one dialysing fluid concentrate (K1, K2) therefrom (see Fig. 1);
- a means (control and calculating unit 24) for setting a dialysing fluid flow rate Q_{db} during a dialysis treatment such that at the end of the pre-set treatment period T_B , the at least one receiving unit (12, 13) is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate (K1, K2) (See Figs. 2a, 2b; page 8, lines 24-26);
- wherein the dialysing fluid flow rate Q_{db} is dependent upon a pre-set volume (M_{fl}) of the at least one dialysing fluid concentrate (K1, K2) at a commencement of a dialysis treatment period, the first pre-set volumetric ratio (V_1 of acid concentrate to water), and the pre-set treatment period T_B (page 8, lines 26-29).

Independent claim 26 is directed to an apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid. Specifically, with reference to example embodiments within the scope of claim 26 described in the specification and illustrated in the figures, claim 26 is directed to an apparatus for supplying a dialyser (1) of a dialysis unit with a dialysing fluid, wherein a dialysis treatment period equals a pre-set time interval T_{B1} plus a remaining dialysis treatment period T_{B2} , the apparatus comprising:

- at least one receiving unit (canister 12, bag 13) for receiving only at least one dialysing fluid concentrate (K1, K2) (page 6, lines 10-12; Fig. 1);

¹ Page and line numbers refer to the substitute specification filed July 22, 2005.

- means (38) for providing water (W) for a dilution of the at least one dialysing fluid concentrate (page 7, lines 29-32; Fig. 1);
- means (mixing chamber 15 and proportioning pumps 17, 18, 20) for mixing the at least one dialysing fluid concentrate (K1, K2) and the water (W) in a first pre-set volumetric ratio to prepare the dialysing fluid (page 7, lines 29-32), said means for mixing (15, 17, 18, 20) connected to the at least one receiving unit (12, 13) and configured to receive the at least one dialysing fluid concentrate (K1, K2) therefrom (see Fig. 1);
- a means (control and calculating unit 24) for supplying the dialysing fluid to the dialyser at a pre-set dialysing fluid flow rate Qd_{b1} over the pre-set time interval T_{B1} such that an amount of the at least one dialysing fluid concentrate (K1, K2) remaining in the at least one receiving unit (12, 13) at the end of the pre-set time interval T_{B1} can be determined from the pre-set volume of the at least one dialysing fluid concentrate (K1, K2) at the commencement of the dialysis treatment period and an amount of the at least one dialysing fluid concentrate used up during the dialysis treatment period (See Figs. 3a, 3b, page 10, lines 5-10), and
- a means (24) for setting a dialysing fluid flow rate Qd_v over the remaining dialysis treatment period T_{B2} which depends upon a volume of the at least one dialysing fluid concentrate (K1, K2) in the at least one receiving unit (12, 13) at the end of the pre-set time interval of the dialysis treatment T_{B1} , the first pre-set volumetric ratio, and the remaining dialysis treatment period T_{B2} , such that at the end of the dialysis treatment period, the at least one receiving unit (12, 13) is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate (See Figs. 3a, 3b, page 10, lines 20-24).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claim 24 is indefinite under 35 USC 112, 2nd paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Whether claims 23-30, 35, 39 and 40 are anticipated under 35 U.S.C. 102(b) by U.S. Patent 5,744,027 to Connell et al. ("Connell").

ARGUMENT

Rejection Under 35 USC 112, 2nd paragraph

Claim 24

The Examiner rejected claim 24 for reciting the limitation of a “control and calculating unit,” for allegedly lacking antecedent basis. Claim 24 was amended in the response filed on August 5, 2010 to remove the limitation of a “control and calculating unit” and replace it with “means for setting.” Applicants believe this rejection is now moot.

Rejection Under 35 USC §102(b) Over US Patent 5,744,027 to Connell et al. (“Connell”)

Independent Claims 23 and 26 and Dependent Claims 24, 25, 27-30, 35, 39 and 40

Connell fails to disclose “a means for setting a dialysing fluid flow rate Q_{d_b} during a dialysis treatment *such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate,*” as recited in claim 23. Connell also fails to disclose “a means for setting a dialysing fluid flow rate Q_{d_v} ...*such that at the end of the dialysis treatment period, the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate,*” as recited in claim 26.

The Examiner has identified the receiving unit as the third concentrate supply 116, the means for providing water as water source 82, and the means for mixing as mixing chamber 120 in Connell. Although Connell discloses a UF/PROP system 516 that controls the dialysis flow rate, there is no disclosure that the system 516 adjusts the flow rate *so that* the receiving unit is empty or contains a pre-set residual volume of the concentrate at the end of the treatment time. Although Connell may disclose that the equalizer chambers are emptied, there is no disclosure of the concentrate supply 116 being emptied of concentrate.

The Examiner states that “[r]egarding the limitations reciting *configured to* language, the examiner considers these to be statements with regard to intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use

must result in a *structural difference* between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. (MPEP § 211.02)” (Office Action, page 3).

However, claims 23 and 26 invoke “means plus function” claim language as authorized by 35 U.S.C. § 112, paragraph 6. According to the MPEP, “the application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the identical function specified in the claim.” MPEP § 2182 (emphasis added). “Such a limitation cannot be met by an element in a reference that performs a different function, even though it may be part of a device embodying the same general overall concept.” *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1445 n. 5 (Fed. Cir. 1984) (emphasis added); *see also Ishida Co., Ltd. v. Taylor*, 221 F.3d 1310, 1316 (Fed. Cir. 2000) (literally meeting a means-plus-function clause “requires that the accused device perform a function identical to that identified in the means clause” (emphasis added)). Only “if a prior art reference teaches identity of function to that specified in a claim, then under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.” MPEP § 2182 (emphasis added). According to the MPEP, the first step in making a prima facie case of equivalence is to determine if the prior art element performs the function specified in the claim. MPEP § 2183. Applicants submit that the Examiner has ignored the initial step of the analysis, as the device in Connell does not perform an identical function.

According to case law, the prior art reference must perform the complete identical function as recited in the claims. In *Ex Parte Powers*, the Board held that “[f]or a means-plus-function limitation to read on a device, the device must employ means identical or equivalent to the corresponding structures, materials, or acts described in the specification and must also perform the identical function as specified in the limitation.” *Ex Parte Powers*, 2003 Pat. App. LEXIS 52, 6 (BPAI 2003). The Board found that “Kirschke’s metal ruler 40 and ruler slide 41 perform the identical function specified by the limitation at issue, i.e., they are reflective and changeable in response to downward movement of the vertical test arm so that a user can direct a focused light source toward them and observe when the pipeline inspection device is far from the user, thereby indicating to the user any downward movement of the vertical test arm.” *Id.* The

claim at issue recited the following limitation: “reflective means changeable in response to downward movement of the vertical test arm, so that a user can direct a focused light source toward them and thereby observe the state of said reflective means when the pipeline inspection device is far from the user, thereby indicating to the user any downward movement of the vertical test arm.” *Id.* at 2. In *Ex Parte Powers* the Board thus specified that the function of a means-plus-function limitation includes *all the modifying language* following “reflective means” in the claim.

Additionally, the Federal Circuit in *IMS Tech. Inc. v. Haas Automation, Inc.* held that the full function of a means-plus-function clause must be given weight. In that case, the claim recited an “interface means for transferring a control program and control parameters from an external medium into said alterable memory.” *IMS Tech. Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1427 (Fed. Cir. 2000). The Appellant argued that the corresponding structure needed only to perform a “transferring” function, regardless of whether the transferring was done “from an external medium.” *Id.* at 1431. The Federal Circuit disagreed. The Federal Circuit held that the full means-plus-function clause, including the phrase “from an external medium,” must be given weight. Thus, the Court ruled that “the claims require the interface means to transfer data to the RAM *from an external medium*, i.e., a tape cassette, not just from the tape cassette transport.” *Id.* (emphasis added).

As discussed above, Connell does not perform the identical function as claimed in the pending claims because Connell does not disclose “a means for setting a dialysing fluid flow rate Q_{d_b} during a dialysis treatment such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate; wherein the dialysing fluid flow rate Q_{d_b} is dependent upon a pre-set volume of the at least one dialysing fluid concentrate at a commencement of a dialysis treatment period, the first pre-set volumetric ratio, and the pre-set treatment period T_B ,” as recited in claim 23 or “a means for supplying the dialysing fluid to the dialyser at a pre-set dialysing fluid flow rate Q_{d_b1} over the pre-set time interval T_{B1} such that an amount of the at least one dialysing fluid concentrate remaining in the at least one receiving unit at the end of the pre-set time interval T_{B1} can be determined from the pre-set volume of the at least one dialysing fluid concentrate at the commencement of the dialysis treatment period and an amount of the at least one dialysing fluid concentrate used up during the dialysis treatment period, and a means for setting a dialysing fluid

flow rate Q_d , over the remaining dialysis treatment period T_{B2} which depends upon a volume of the at least one dialysing fluid concentrate in the at least one receiving unit at the end of the pre-set time interval of the dialysis treatment T_{B1} , the first pre-set volumetric ratio, and the remaining dialysis treatment period T_{B2} , such that at the end of the dialysis treatment period, the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate,” as recited in claim 26.

Thus, the Examiner cannot simply ignore part of the means-plus-function limitation. According to case law, the limitation, “such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate” is part of the means for detecting and cannot be ignored as simply “intended use.” Thus, Connell does not disclose or suggest all the limitations of independent claims 23 and 26, and all claims dependent therefrom.

CONCLUSION

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's decision rejecting claims 23-30, 35, 39 and 40 and direct the Examiner to pass the case to issue.

Respectfully submitted,

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CLAIMS APPENDIX

23. An apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid, the apparatus comprising:

at least one receiving unit for receiving only at least one dialysing fluid concentrate;

means for providing water for a dilution of the at least one dialysing fluid concentrate;

means for mixing the at least one dialysing fluid concentrate and the water in a first pre-set volumetric ratio to prepare the dialysing fluid, said means for mixing connected to the at least one receiving unit and configured to receive the at least one dialysing fluid concentrate therefrom;

a means for setting a dialysing fluid flow rate Q_{d_b} during a dialysis treatment such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate;

wherein the dialysing fluid flow rate Q_{d_b} is dependent upon a pre-set volume of the at least one dialysing fluid concentrate at a commencement of a dialysis treatment period, the first pre-set volumetric ratio, and the pre-set treatment period T_B .

24. The apparatus of claim 23, wherein the means for setting a dialysing fluid flow rate Q_{d_b} determines the dialysis fluid flow rate Q_{d_b} before the commencement of the dialysis treatment period from the pre-set volume of the at least one dialysing fluid concentrate at the commencement of the dialysis treatment period, the first pre-set volumetric ratio, and the pre-set treatment period T_B ,

wherein the means for setting is configured to set the dialysing fluid flow rate Q_{d_b} over the pre-set treatment period T_B such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate.

25. The apparatus of claim 23, further comprising:

a means for testing the apparatus over a pre-set time interval T_{test} before the commencement of the dialysis treatment period, and

a means for determining a volume of the at least one dialysing fluid concentrate in the at least one receiving unit from the pre-set volume of the at least one dialysing fluid concentrate at the commencement of the dialysis treatment period and a volume of the at least one dialysing fluid concentrate used during the pre-set time interval T_{rest} .

26. An apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid, wherein a dialysis treatment period equals a pre-set time interval T_{B1} plus a remaining dialysis treatment period T_{B2} , the apparatus comprising:

- at least one receiving unit for receiving only at least one dialysing fluid concentrate;
- means for providing water for a dilution of the at least one dialysing fluid concentrate;
- means for mixing the at least one dialysing fluid concentrate and the water in a first pre-set volumetric ratio to prepare the dialysing fluid, said means for mixing connected to the at least one receiving unit and configured to receive the at least one dialysing fluid concentrate therefrom;

- a means for supplying the dialysing fluid to the dialyser at a pre-set dialysing fluid flow rate $Q_{d_{B1}}$ over the pre-set time interval T_{B1} such that an amount of the at least one dialysing fluid concentrate remaining in the at least one receiving unit at the end of the pre-set time interval T_{B1} can be determined from the pre-set volume of the at least one dialysing fluid concentrate at the commencement of the dialysis treatment period and an amount of the at least one dialysing fluid concentrate used up during the dialysis treatment period, and

- a means for setting a dialysing fluid flow rate Q_d over the remaining dialysis treatment period T_{B2} which depends upon a volume of the at least one dialysing fluid concentrate in the at least one receiving unit at the end of the pre-set time interval of the dialysis treatment T_{B1} , the first pre-set volumetric ratio, and the remaining dialysis treatment period T_{B2} , such that at the end of the dialysis treatment period, the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate.

27. The apparatus of claim 24, further comprising:

- means for discharging the pre-set residual volume of the at least one dialysing fluid concentrate to waste via a waste discharge outlet;

wherein at the end of the pre-set treatment period T_B the at least one receiving unit contains the pre-set residual volume of the at least one dialysing fluid concentrate, and the pre-set residual volume is capable of being discharged to the waste discharge outlet.

28. The apparatus of claim 27, further comprising:

means for mixing the pre-set residual volume of the at least one dialysing fluid concentrate with water in a second pre-set volumetric ratio;

wherein the pre-set residual volume is capable of being diluted with water before the pre-set residual volume is discharged to the waste discharge outlet.

29. The apparatus of claim 24, wherein at the end of the pre-set treatment period T_B , the at least one receiving unit is empty.

30. The apparatus of claim 23, further comprising:

means for inputting data relevant to the pre-set volume of the at least one dialysing fluid concentrate at the commencement of a dialysis treatment period, the first pre-set volumetric ratio, and the pre-set treatment period.

35. The apparatus of claim 23, wherein the at least one receiving unit comprises two receiving units.

39. The apparatus of claim 26, further comprising:

means for discharging the pre-set residual volume of the at least one dialysing fluid concentrate to waste via a waste discharge outlet;

wherein at the end of the remaining dialysis treatment period T_{B2} the at least one receiving unit contains the pre-set residual volume of the at least one dialysing fluid concentrate, and the pre-set residual volume is capable of being discharged to the waste discharge outlet.

40. The apparatus of claim 26, wherein at the end of the remaining dialysis treatment period T_{B2} , the at least one receiving unit is empty.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.